P2 945386

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

March 05, 2003

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY OF THE BELOW IDENTIFIED INTERNATIONAL APPLICATION AS ORIGINALLY FILED AND ANY CORRECTIONS THERETO FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE ACTING AS A RECEIVING OFFICE UNDER THE PATENT COOPERATION TREATY.

APPLICATION NUMBER: ***PCT/US02/02493***
FILING DATE: ***JANUARY 28, 2002.***

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

N. WOODSON
Certifying Officer

HOME COPY

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No. PCT/US 02/02493 (28.01.02)

International Filing Date 28 JAN 2002

PCT INTERNATIONAL APPLICATION

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* 6970.01

Box No. I TITLE OF INVENTION

FLUID AND BIOAEROSOL MANAGEMENT

Box No. II APPLICANT ☐ This person is also inventor

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

JLJ MEDICAL DEVICES INTERNATIONAL, LLC
6504 Walker Street
Suite 212
St. Louis Park, Minnesota 55426
US

Telephone No. (952) 929-3881
Facsimile No. (952) 929-3984
Teleprinter No. N/A
Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

DROGUE, Jeffrey K.
5117 Washburn Avenue South
Minneapolis, Minnesota 55410
US ▲

This person is:
☐ applicant only
☒ applicant and inventor
☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

BRUHN, David E.
Dorsey & Whitney LLP
Suite 1500
50 South Sixth Street
Minneapolis, Minnesota 55402-1498
US

Telephone No. (612) 340.6317
Facsimile No. (612) 340.8856
Teleprinter No. N/A
Agent's registration No. with the Office 36,762

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

▲ 30 US

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

SCHULTZ, Leonard S.
11036 Boone Circle
Bloomington, Minnesota 55438
US

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office:

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of:
- ☐ all designated States
- ☐ all designated States except the United States of America
- ☒ the United States of America only
- ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

THOMPSON, Barry M.
6258 Fernbrook Lane North
Maple Grove, Minnesota 55311
US

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office:

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of:
- ☐ all designated States
- ☐ all designated States except the United States of America
- ☒ the United States of America only
- ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office:

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of:
- ☐ all designated States
- ☐ all designated States except the United States of America
- ☐ the United States of America only
- ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office:

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of:
- ☐ all designated States
- ☐ all designated States except the United States of America
- ☐ the United States of America only
- ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No. V DESIGNATION OF STATES *Mark the applicable check-boxes below; at least one must be marked.*

The following designations are hereby made under Rule 4.9(a)

Regional Patent

☒ **AP** **ARIPO Patent:** **GH** Ghana, **GM** Gambia, **KE** Kenya, **LS** Lesotho, **MW** Malawi, **MZ** Mozambique, **SD** Sudan, **SL** Sierra Leone, **SZ** Swaziland, **TZ** United Republic of Tanzania, **UG** Uganda, **ZM** Zambia, **ZW** Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

☒ **EA** **Eurasian Patent:** **AM** Armenia, **AZ** Azerbaijan, **BY** Belarus, **KG** Kyrgyzstan, **KZ** Kazakhstan, **MD** Republic of Moldova, **RU** Russian Federation, **TJ** Tajikistan, **TM** Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT

☒ **EP** **European Patent:** **AT** Austria, **BE** Belgium, **CH & LI** Switzerland and Liechtenstein, **CY** Cyprus, **DE** Germany, **DK** Denmark, **ES** Spain, **FI** Finland, **FR** France, **GB** United Kingdom, **GR** Greece, **IE** Ireland, **IT** Italy, **LU** Luxembourg, **MC** Monaco, **NL** Netherlands, **PT** Portugal, **SE** Sweden, **TR** Turkey, and any other State which is a Contracting State of the European Patent Convention and of the PCT

☒ **OA** **OAPI Patent:** **BF** Burkina Faso, **BJ** Benin, **CF** Central African Republic, **CG** Congo, **CI** Côte d'Ivoire, **CM** Cameroon, **GA** Gabon, **GN** Guinea, **GQ** Equatorial Guinea, **GW** Guinea-Bissau, **ML** Mali, **MR** Mauritania, **NE** Niger, **SN** Senegal, **TD** Chad, **TG** Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

☒ **AE** United Arab Emirates	☒ **GM** Gambia	☒ **NZ** New Zealand
☒ **AG** Antigua and Barbuda	☒ **HR** Croatia	☒ **OM** Oman
☒ **AL** Albania	☒ **HU** Hungary	☒ **PH** Philippines
☒ **AM** Armenia	☒ **ID** Indonesia	☒ **PL** Poland
☒ **AT** Austria	☒ **IL** Israel	☒ **PT** Portugal
☒ **AU** Australia	☒ **IN** India	☒ **RO** Romania
☒ **AZ** Azerbaijan	☒ **IS** Iceland	☒ **RU** Russian Federation
☒ **BA** Bosnia and Herzegovina	☒ **JP** Japan	
☒ **BB** Barbados	☒ **KE** Kenya	☒ **SD** Sudan
☒ **BG** Bulgaria	☒ **KG** Kyrgyzstan	☒ **SE** Sweden
☒ **BR** Brazil	☒ **KP** Democratic People's Republic of Korea	☒ **SG** Singapore
☒ **BY** Belarus		☒ **SI** Slovenia
☒ **BZ** Belize	☒ **KR** Republic of Korea	☒ **SK** Slovakia
☒ **CA** Canada	☒ **KZ** Kazakhstan	☒ **SL** Sierra Leone
☒ **CH & LI** Switzerland and Liechtenstein	☒ **LC** Saint Lucia	☒ **TJ** Tajikistan
☒ **CN** China	☒ **LK** Sri Lanka	☒ **TM** Turkmenistan
☒ **CO** Colombia	☒ **LR** Liberia	☒ **TN** Tunisia
☒ **CR** Costa Rica	☒ **LS** Lesotho	☒ **TR** Turkey
☒ **CU** Cuba	☒ **LT** Lithuania	☒ **TT** Trinidad and Tobago
☒ **CZ** Czech Republic	☒ **LU** Luxembourg	
☒ **DE** Germany	☒ **LV** Latvia	☒ **TZ** United Republic of Tanzania
☒ **DK** Denmark	☒ **MA** Morocco	☒ **UA** Ukraine
☒ **DM** Dominica	☒ **MD** Republic of Moldova	☒ **UG** Uganda
☒ **DZ** Algeria		☒ **US** United States of America
☒ **EC** Ecuador	☒ **MG** Madagascar	
☒ **EE** Estonia	☒ **MK** The former Yugoslav Republic of Macedonia	☒ **UZ** Uzbekistan
☒ **ES** Spain		☒ **VN** Viet Nam
☒ **FI** Finland	☒ **MN** Mongolia	☒ **YU** Yugoslavia
☒ **GB** United Kingdom	☒ **MW** Malawi	☒ **ZA** South Africa
☒ **GD** Grenada	☒ **MX** Mexico	☒ **ZM** Zambia
☒ **GE** Georgia	☒ **MZ** Mozambique	☒ **ZW** Zimbabwe
☒ **GH** Ghana	☒ **NO** Norway	

Check-boxes below reserved for designating States which have become party to the PCT after issuance of this sheet:

☐	☐	☐
☐	☐	☐

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)*

Supplemental Box *If the Supplemental Box is not used, this sheet should not be included in the request.*

1 *If in any of the Boxes, except Boxes Nos. VIII(i) to (vi) for which a special continuation box is provided, **the space is insufficient** to furnish all the information: in such case, write "Continuation of Box No ..." (indicate the number of the Box) and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient, in particular:*

*(i) **if more than two persons are to be indicated as applicants and/or inventors** and no "continuation sheet" is available: in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below:*

*(ii) if, in Box No. II or in any of the sub-boxes of Box No. III, the indication **"the States indicated in the Supplemental Box"** is checked: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is applicant:*

*(iii) if, in Box No. II or in any of the sub-boxes of Box No. III, **the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America**: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is inventor:*

*(iv) if, in addition to the agent(s) indicated in Box No. IV, there are **further agents**: in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV:*

*(v) if, in Box No. V, the name of any State (or OAPI) is accompanied by the indication "**patent of addition**," or "**certificate of addition**," or if, in Box No. V, the name of the United States of America is accompanied by an indication "**continuation**" or "**continuation-in-part**": in such case, write "Continuation of Box No. V" and the name of each State involved (or OAPI), and after the name of each such State (or OAPI), the number of the parent title or parent application and the date of grant of the parent title or filing of the parent application:*

*(vi) if, in Box No. VI, there are **more than five earlier applications whose priority is claimed**: in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI.*

2. *If, with regard to the **precautionary designation statement** contained in Box No. V, the applicant wishes to exclude any State(s) from the scope of that statement: in such case, write "Designation(s) excluded from precautionary designation statement" and indicate the name or two-letter code of each State so excluded.*

Continuation of Box IV:

ACKLEY, James H.; BROWN, Ronald J.; BRUHN, David E.; CHAPIK, Daniel G.; FRONEK, David N.; HANKES, Theresa H.; HEINRICHS, Lori J.; HEMPHILL, Stuart R.; KRAUS, Jason R.; LEVITT, Kenneth E.; MARKS, Scott A.; PADMANABHAN, Devan V.; ROTHENBERGER, Scott D.; SOLBERG, Sean D.; SULLIVAN, Gerald H.; TOLENTINO, Jonar J.; TUTTLE, Jon F.; XU, Min

Dorsey & Whitney LLP
Suite 1500
50 South Sixth Street
Minneapolis, Minnesota 55402-1498
US

Telephone: 612-340-2600
Fax: 612-340-8856
Teleprinter: N/A

Box No. VI PRIORITY CLAIM

The priority of the following earlier application(s) is hereby claimed:

Filing date of earlier application *(day/month/year)*	Number of earlier application	Where earlier application is:		
		national application: country	regional application:* regional Office	international application: receiving Office
item (1) 29 January 2001 (29.01.2001)	60/264,871	US		
item (2)				
item (3)				
item (4)				
item (5)				

☐ Further priority claims are indicated in the Supplemental Box.

The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of this international application is the receiving Office)* identified above as:

☒ all items ☐ item (1) ☐ item (2) ☐ item (3) ☐ item (4) ☐ item (5) ☐ other, see Supplemental Box

* *Where the earlier application is an ARIPO application, indicate at least one country party to the Paris Convention for the Protection of Industrial Property or one Member of the World Trade Organization for which that earlier application was filed (Rule 4.10(b)(ii)):* . . . .

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used)*:

ISA / US

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority)*:

Date *(day/month/year)* Number Country *(or regional Office)*

Box No. VIII DECLARATIONS

The following **declarations** are contained in Boxes Nos. VIII (i) to (v) *(mark the applicable check-boxes below and indicate in the right column the number of each type of declaration)*: Number of declarations

☐ Box No. VIII (i)	Declaration as to the identity of the inventor	:
☐ Box No. VIII (ii)	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	:
☐ Box No. VIII (iii)	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	:
☐ Box No. VIII (iv)	Declaration of inventorship (only for the purposes of the designation of the United States of America)	:
☐ Box No. VIII (v)	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	:

Box No. IX CHECK LIST; LANGUAGE OF FILING

This international application **contains**:

(a) the following number of **sheets in paper form**:

request (including declaration sheets)	:	6
description (excluding sequence listing part)	:	14
claims	:	4
abstract	:	1
drawings	:	3
Sub-total number of sheets	:	28
sequence listing part of description *(actual number of sheets if filed in paper form, whether or not also filed in computer readable form: see (b) below)*	:	0
Total number of sheets	:	28

(b) sequence listing part of description filed in **computer readable form**

(i) ☐ only (under Section 801(a)(i))

(ii) ☐ in addition to being filed in paper form (under Section 801(a)(ii))

Type and number of carriers (diskette, CD-ROM, CD-R or other) on which the sequence listing part is contained *(additional copies to be indicated under item 9(ii), in right column)*: .....

This international application is **accompanied by** the following item(s) *(mark the applicable check-boxes below and indicate in right column the number of each item)*:

		Number of items
1. ☒ fee calculation sheet	:	1
2. ☐ original separate power of attorney	:	
3. ☐ original general power of attorney	:	
4. ☐ copy of general power of attorney; reference number, if any:	:	
5. ☐ statement explaining lack of signature	:	
6. ☐ priority document(s) identified in Box No. VI as item(s):	:	
7. ☐ translation of international application into *(language)*:	:	
8. ☐ separate indications concerning deposited microorganism or other biological material	:	
9. ☐ sequence listing in computer readable form (indicate also type and number of carriers (diskette, CD-ROM, CD-R or other))		
(i) ☐ copy submitted for the purposes of international search under Rule 13*ter* only (and not as part of the international application)	:	
(ii) ☐ *(only where check-box (b)(i) or (b)(ii) is marked in left column)* additional copies including, where applicable, the copy for the purposes of international search under Rule 13*ter*	:	
(iii) ☐ together with relevant statement as to the identity of the copy or copies with the sequence listing part mentioned in left column	:	
10. ☒ other *(specify)*: Cert Ex Mail; Receipt Postcard	:	2

Figure of the drawings which should accompany the abstract: Figure 3

Language of filing of the international application: English

Box No. X SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

David E Bruhn Reg No 36,762

BRUHN, David E. (Agent)

For receiving Office use only

1. Date of actual receipt of the purported international application: (28.01.02) JC10 Rec'd PCT/PTO 28 JAN 2002

2. Drawings: ☐ received: ☐ not received:

3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:

4. Date of timely receipt of the required corrections under PCT Article 11(2):

5. International Searching Authority (if two or more are competent): ISA / US

6. ☐ Transmittal of search copy delayed until search fee is paid

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

PCT/US02/02493
RO/US 11 APR 2002

PCT

POWER OF ATTORNEY

(for an international application filed under the Patent Cooperation Treaty)

(PCT Rule 90.4)

The undersigned applicant(s) *(Names should be indicated as they appear in the request)*:

JLJ Medical Devices International, LLC
6504 Walker Street
Suite 212
St. Louis Park, Minnesota 55426
US

hereby appoints (appoint) the following person as: ☒ agent ☐ common representative

Name and address
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

ACKLEY, James H.; BROWN, Ronald J.; BRUHN, David E.; CHAPIK, Daniel G.; FRONEK, David N.; HANKES, Theresa K.; HEINRICHS, Lori J.; HEMPHILL, Stuart R.; KRAUS, Jason R.; LEVITT, Kenneth E.; MARKS, Scott A.; PADMANABHAN, Devan V.; ROTHENBERGER, Scott D.; SOLBERG, Sean D.; SULLIVAN, Gerald H.; TOLENTINO, Jonar J.; TUTTLE, Jon F.; XU, Min

Dorsey & Whitney LLP, Suite 1500, 50 South Sixth Street, Minneapolis, Minnesota 55402-1498, US
Telephone: 612-340-2600; Facsimile: 612-340-8856

to represent the undersigned before

☒ all the competent International Authorities
☐ the International Searching Authority only
☐ the International Preliminary Examining Authority only

in connection with the international application identified below:

Title of the invention: FLUID AND BIOAEROSOL MANAGEMENT

Applicant's or agent's file reference: 6970.01

International application number (if already available): PCT/US02/02493

filed with the following Office United States Patent and Trademark Office as receiving Office and to make or receive payments on behalf of the undersigned.

Signature of the applicant(s) *(where there are several applicants, each of them must sign; next to each signature, indicate the name of the person signing and the capacity in which the person signs, if such capacity is not obvious from reading the request or this power)*:

(Signature)
Name: Barry Thompson

Title: President & Ch. Mgr.

JLJ Medical Devices International, LLC

Date: 3-18-02

Form PCT/Model of power of attorney (for a given international application) (July 1992)

This sheet is not part of and does not count as a sheet of the international application.

PCT

FEE CALCULATION SHEET

Annex to the Request

For receiving Office use only

PCT/US 02/02493

International Application No.

Date stamp of the receiving Office (28 01.02)

Applicant's or agent's file reference: 6970.01

Applicant

JLJ MEDICAL DEVICES INTERNATIONAL, LLC

CALCULATION OF PRESCRIBED FEES

	Amount		RO use
1. TRANSMITTAL FEE	240.00	T	240
2. SEARCH FEE	700.00	S	700

International search to be carried out by ____

(If two or more International Searching Authorities are competent to carry out the international search, indicate the name of the Authority which is chosen to carry out the international search.)

3. INTERNATIONAL FEE

Basic Fee

Where item (b) of Box No. IX applies, enter **Sub-total number of sheets**
Where item (b) of Box No. IX does not apply, enter **Total number of sheets** ____

				Amount		RO use
b1	first 30 sheets			382.00	b1	407
b2	0 (number of sheets in excess of 30)	x	9.00 (fee per sheet)	0	b2	
b3	additional component (only if sequence listing part of description is filed in computer readable form under Section 801(a)(i), or both in that form and on paper, under Section 801(a)(ii)): 400	x	____ (fee per sheet)		b3	–
	Add amounts entered at b1, b2 and b3 and enter total at B			382.00	B	407

Designation Fees

The international application contains 93 designations.

			Amount		RO use
5 (number of designation fees payable *(maximum 5)*)	x	82.00 (amount of designation fee)	410.00	D	440
Add amounts entered at B and D and enter total at I			792.00	I	847

(Applicants from certain States are entitled to a reduction of 75% of the international fee. Where the applicant is (or all applicants are) so entitled, the total to be entered at I is 25% of the sum of the amounts entered at B and D.)

	Amount		RO use
4. FEE FOR PRIORITY DOCUMENT *(if applicable)*	15.00	P	15
5. TOTAL FEES PAYABLE — Add amounts entered at T, S, I and P, and enter total in the TOTAL box	1,747.00	TOTAL	1302

☒ The designation fees are not paid at this time.

MODE OF PAYMENT

☐ authorization to charge deposit account (see below) ☐ postal money order ☐ cash ☐ coupons
☐ cheque ☐ bank draft ☐ revenue stamps ☐ other *(specify)*:

AUTHORIZATION TO CHARGE (OR CREDIT) DEPOSIT ACCOUNT

(This mode of payment may not be available at all receiving Offices)

☐ Authorization to charge the total fees indicated above.

☐ *(This check-box may be marked only if the conditions for deposit accounts of the receiving Office so permit)* Authorization to charge any deficiency or credit any overpayment in the total fees indicated above.

☐ Authorization to charge the fee for priority document.

Receiving Office: RO/ USPTO

Deposit Account No.: 04-1420

Date: 28 January 2002

Name: David E. Bruhn

Signature: [signature]

Reg No 36,762

Form PCT/RO/101 (Annex) (January 2002)

See Notes to the fee calculation sheet

01/31/2002 DGORDON 00000003 041420 PCT/US02/0
01 FC:099 Sale Ref: 00000003 DAH: 041420 PCT/US02/02493
48.00 OP

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Applicant(s): JLJ MEDICAL DEVICES INTERNATIONAL, LLC	Docket No. 6970.01

Serial No.	Filing Date	Examiner	Group Art Unit
Not Yet Known	Herewith	Not Yet Known	Not Yet Known

Invention: **FLUID AND BIOAEROSOL MANAGEMENT**

I hereby certify that this **PCT Request (6); Fee Calc (1); Spec (19, w/4 pgs Claims, 1 pg Abstrac); Drwgs (3); Pstcrd**
(Identify type of correspondence)

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: The Commissioner of Patents and Trademarks, Washington, D.C. 20231-0001 on **28 January 2002**
(Date)

Brian Ballard
(Typed or Printed Name of Person Mailing Correspondence)

(Signature of Person Mailing Correspondence)

EV 040213114 US
("Express Mail" Mailing Label Number)

Note: Each paper must have its own certificate of mailing.

PCT
New International Application
Inventory of Unscannable or Missing Items

Serial Number PCT/US 02/02493

Check This Column if Item Is Present	Item	Check This Column if Item Is Missing on Filing
✓	Return Receipt Postcard	
	Check (amount $ 1,717.00)	✓
	PCT EASY Diskette	
	DNA Diskette	
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OPERATED BY: Renetta

Title: Fluid and Bioaerosol Management

The present invention relates to devices and methods for material handling and, in one embodiment, a fluid, i.e., gas and liquid, and bioaerosol management system and method suitable for use in the medical field. The present invention encompasses a method of handling, collecting, managing, measuring and/or disposing of fluids, including gases and liquids and, in some embodiments, solids.

The present invention may be well suited for use in the medical field, particularly in surgery, whether surgical procedures are being carried out in an operating room(s) or other clinical locations. It is well suited for use in controlling the flow of gases (e.g., air, inert gases, oxygen, etc.), liquids, fluids and bioaerosol and/or biohazardous material used or produced during surgical procedures. It provides for the removal of bioaerosols, fluids and liquids which are associated with surgical procedures, and provides for assessing or measuring the quantity of liquids, e.g., saline solution, blood, plasma, ascites and the like, produced or used during surgical procedures.

U.S. Patents 5,019,060 (Goosen), 4,184,510 (Murry et al.), 4,704,106 (Shave et al.), 5,345,928 (Lindkvist) and 5707,086 Treu et al.) disclose examples of the use of vacuum in the medical field, including a liquid collection device for use with surgical procedures (the 5,019,060 patent). The disclosures of these five patents, particularly as to the use of vacuum in the medical field, are incorporated herein by reference.

U.S. Patents 6,131,571 (Lampotang et al.), 5,836,909 (Cosmescu) and 4,453,937 (Kurtz et al.), disclose the use of various type of flow measuring devices including air flow meters (the 4,453,937 patent), and/or pressure and/or flow and fluid sensors (the 5,836,909 patent). The disclosures of these three patents, particularly as to the flow measuring and sensing devices, is incorporated herein by reference.

In one embodiment, the present invention comprises a system comprising a centralized evacuation system, one or more "end effectors" and a connector for operably coupling the one or more end effectors to the centralized evacuation system.

In one embodiment, the present invention comprises a connector for operably coupling one or more end effectors to a wall port of a central vacuum system, wherein the connector facilitates the coupling of the one or more end effectors and is adapted to receive both gaseous and liquid material. In some embodiments, the connector is adapted to separate gaseous and liquid material and, after the separation, collect and measure the quantity of liquid material, and, in some embodiments, to measure and/or display the quantity of such gaseous and liquid material. In some embodiments, the connector is adapted to modify or adjust the vacuum pressure provided by the central vacuum and/or the flow rate of the material being picked up.

One centralized evacuation system of a type suitable for use in the system of the present invention is described in U.S. Patent 5,264,026, the disclosures of which patent are incorporated herein by reference. The patent discloses a

centralized system for removing the plume resulting from surgical procedures, wherein the plume is drawn away from the surgical field by a vacuum. The disclosed system is suitable for vacuuming or suctioning both liquids and gas and includes a central suction device that includes a centrifugal separator and a vacuum producer. The central system is "central" because it is located in a mechanical room which is removed from or remote with respect to one or more operating rooms served by the vacuum system. Such systems include a suitable network of conduits or piping, and typically include wall inlets, ports or wall-mounted boxes with openings or ports for connecting a flexible conduit to an end effector. These end effectors may take various forms including that described in U.S. Patent 4,921,492, the disclosure of which is incorporated herein by reference, and/or various embodiments thereof. As used herein the term "end effectors" is intended to encompass any structure adapted to provide for bringing a vacuum adjacent to a material or item to pick or suck up the material or item, and may include typical tubular wands or cautery tools carrying generally tubular devices which may be positioned adjacent to a surgical field to provide for removal of bioaerosol gases and/or liquids. The term is also intended to encompass such structures and devices adapted to be applied to picking up or handling both liquid and gaseous material and, in some instances, solid material.

Brief Description of the Figures

Figure 1 depicts one embodiment of a system in accordance with the present invention.

Figure 2 depicts one embodiment of a connector in accordance with the present invention.

Figure 3 is an elevational view of the connector depicted in Figure 2.

Figure 4 depicts one embodiment of an end effector with a fluid flow depicted, and Figure 4a depicts another end effector.

Figure 5 depicts an adaptor for coupling to the connector for adapting the present invention to pick up solid material.

Figure 6 depicts a decontamination container in accordance with the present invention.

Description

Features and advantages of the fluid and bioaerosol device and method of the present invention will become apparent and understood with reference to the above-noted drawings, this description and the descriptive material enclosed herewith, including the described embodiment of a connector or adaptor device for use in the system of the present invention.

With regard to fastening, mounting, attaching or connecting the components of the system of the present invention to form the connector or the system as a whole, unless specifically described otherwise, such are intended to encompass conventional fasteners such as screws, nut and bolt connectors, snap rings, clamps, such as hose clamps, screw clamps and the like, rivets, toggles, pins and the like. Components may also be connected or coupled by welding, friction fitting or deformation. Electrical components and connections may be made using appropriate electrical components and connection methods including conventional components and connectors, suitable display devices such as digital or analog devices, LED's or other light sources and the like, and suitable microprocessor or integrated circuit components. Measuring devices, such as

flow meters, sensors, transducers and the like, whether for measuring volume, flow rate, or liquid or gaseous quantities, may be selected from such measuring devices which are suitable for use in the present invention. Unless otherwise specifically disclosed or taught, materials for making components of the present invention may be selected from appropriate materials such as metal, metallic alloys, fibers, plastics and the like, and appropriate manufacturing and/or production methods including casting, extruding, molding and machining may be used.

As shown in Fig. 1, in one embodiment, the present invention comprises a central vacuum system comprising a central vacuum source 10, one or more end effectors 11 and a connector 12 interposed between the vacuum source 10 and the one or more end effectors 11, wherein the connector has at least one port for receiving gaseous and liquid fluids. In one embodiment, the system includes a suitable pipe or conduit network linking the one or more end effectors to the vacuum source.

In one embodiment, the present invention comprises a system for the handling of fluids, including bodily fluids, such as blood, and/or irrigants, such as saline solutions, within an operating room or clinical setting. Control and handling of such material includes concern for the collection and handling of infectious or disease transmission among operating room personnel. Current methods may not achieve optimum prevention of contamination of nursing and physician personnel. Bioaerosol inhalation is another recognized continuing hazard for patients and operating room personnel.

The present invention, in one embodiment, should reduce or minimize the inhalation of toxic and potentially carcinogenic inhalants and infectious liquids by providing a "no-touch" method of fluid and liquid management for use by operating room personnel. In one embodiment, as depicted in Figure 2, the present invention comprises a central vacuum producing system suitable for collecting both liquid and gaseous material, one or more end effectors for use at a site at which liquid and gaseous material are produced, and a coupling device or connector for operably coupling one or more end effectors to the central vacuum. In this embodiment, the connector may be made of various materials, and may include a suitable liquid monitor or counter such as a flow meter.

In one embodiment, the coupling device or connector 12 of the present invention may include a volumetric measuring device for measuring the amount of bodily fluid or other liquid used during or produced during a surgical procedure. In one embodiment, the connector of the present invention may comprise suitable liquid and air media and may provide for the separation of liquid from gaseous material, yet involve a single suction source suitable for moving or collecting both liquid and gaseous material. See, for example, Figure 1. In some embodiments, a chemical separator and separation method may be used, for example, a suitable media may be disposed in or adjacent to the port(s) of the connector.

In one embodiment, as depicted in Figures 1, 2 and 3, the embodiment of the connector comprises a body having an inlet side 13 and an outlet side 14. The outlet side 14 is suitably adapted to be coupled to a typical vacuum port and the

inlet side 13 is adapted, as depicted in Figure 3, to operably receive or be coupled to one or more end effectors or conduit structures leading to the end effectors. See, for example, the ports depicted in Figure 3. Any suitable coupling or connection methods may be used including "quick-release"-type connectors, Leur-type, detent-type connectors, screw-type connectors or bayonet-type connective structures. Additionally, suitable coupling of conducts and the connector of the present invention may be accomplished by simple friction fitting.

Referring to Figure 1 and 2, within the body of the connector of the present invention in one embodiment there is a separating structure 15 comprising, in the depicted embodiment, a "trap" adjacent to the inlets or ports for receiving liquid as the gas/liquid combination flows across the top of the trap. The trap structure may include a suitable fluid counter, flow meter or monitor 16 for measuring the quantity of liquid passing into and/or through the trap. Both the original liquid/gas combination picked up from a surgical site and the liquid separated from the gas/liquid material are moved by the vacuum generated by the central vacuum system and are pulled into the wall port of the central vacuum system. A pump or other means may be used to move the gas and/or liquid material as well. Every conduit portion or gas and liquid flow path in the connector, or a selected conduit portion or flow path, may have a separate liquid/gas separator structure or feature, or they may be one common separator structure.

In one embodiment, the connector structure of the present invention includes more than one inlet 13, whereby more than one end effector may be coupled to the central vacuum system. Flow rates or vacuum pressures with respect to each of the inlets may be controlled separately to provide for different degrees of suction. For example, in some wand-type end effectors, a lesser degree of suction may be desired, and for certain end effectors, for example, of the "Plume-Away"-type, a greater suction may be desirable to induce a greater flow or to cover a larger area.

In some embodiments, the present invention includes an LED readout 17 for displaying the amount of liquid collected.

In other embodiments of the present invention, the liquid measuring capability may be incorporated in the main-line vacuum portion, i.e., in the wall of the operating room between the connector of the present invention and the wall port, adjacent to the wall port, or in the central mechanical room.

In some embodiments, the "trap" may include a deflector or other suitable device, e.g., a baffle 18, filter, etc., for optimizing the separation of liquid and gaseous material.

In one embodiment, the present invention may be adapted to provide several suction or vacuum related functions: removal of smoke and gaseous byproducts, general cleaning-type functions such as floor and equipment vacuuming, and liquid removal and measurement. These functions may be accomplished by providing a connector structure which connects a single central vacuum system of the type disclosed in U.S. Patent 5,264,026 to various end

effectors or working tools for providing various gas, liquid and/or solid management or pickup using a vacuum pressure, and an adaptor box, depicted in Figure 5, a canister-like structure for collecting and measuring solids, and/or fluid or liquids.

In terms of method or use, in one embodiment, at the end of a surgical case or procedure, the system of the present invention may be used to clean the floor around the operating room table. Typically, such procedures result in material scattered around the floor which may include plastic wrappers or portions thereof, pieces of suture, needles, sponges, etc., as well as liquid material which needs to be picked up and decontaminated. Thus, in one embodiment, the present invention involves a suitable wall mounted vacuum port connected to a central vacuum source, the connector of the present invention, an additional adaptor, or filter, box for collection or separation of solid material and, a suitable conduit connected to the adaptor box. The box may include a suitable baffle 18 structure and/or filters to help ensure that solids collect in the collection portion of the box. In one embodiment, the adaptor box is adapted to precipitate solid material from a flow of liquid fluid, i.e., solids entrained in liquid /air flowing into the adaptor box is precipitated or dropped from the flow, and the flow enters the adaptor of the present invention and liquid is separated from the gas and quantities of liquid are assessed, after which time the flow continues into the conduit leading to the central vacuuming system. In one embodiment, the adaptor box may be reusable in that it can be emptied wherein debris collected may be disposed of conventionally. In one embodiment, the connector and/or the

solids receiving adaptor or filter box may be disposable, i.e., a single use type arrangement or they may be completely reusable or reposeable in that they may last for a couple of years and then need to be replaced.

Referring to Fig. 6, in the instance of reusable and reposeable type connectors and/or filter boxes, the connector and/or filter box structures may be decontaminated before a subsequent use by providing a decontamination unit 20 which comprises a suitable container structure adapted to be coupled to the connector and/or the filter box. For example, the decontamination unit may take the form of a collapsible plastic container which contains a pre-measured amount of a decontaminating, disinfecting, sterilizing or cleaning solution. In one embodiment, the decontamination unit is adapted to be attached to the filter box or to the connector, and the contents are then withdrawn upon actuation of the vacuum source. The container collapses and may be disposed. In some embodiments, the decontamination unit may include a decontaminate flow regulating mechanism or structure, and/or decontaminates may be loaded or contained in separate compartments whereby they may be dispensed together, selectively or sequentially.

As shown in Fig. 3, in one embodiment, the connector unit of the present invention may include an input feature such as a key pad counter 21, touch screen or the like whereby the quantity of liquid vacuumed up is measured and/or displayed, and wherein a known quantity of liquid, e.g., saline, anesthesia materials, etc., may be input into the device. In this embodiment, a calculation feature, e.g., a microprocessor, calculator or the like, is provided whereby the

quantity of input liquid may be subtracted from the total displayed volume to calculate, for example, blood loss or saline use during a surgical procedure. Other calculations may be performed as well, such as calculation of flow rates.

The system and method of the present invention may be used in situations or applications other than the medical field. For example, in certain industries and manufacturing processes, washes or flows of liquid, mists or flows of fluids, are used for cooling or lubricating while a particular procedure is carried out. In these situations, it may be desirable to contain, control or manage the flow of cooling or lubricating material, and/or gases released during such processes, and to measure the quantity of liquid being used and/or consumed by the process. A system of the type of the present invention may be used for this, and may include, for example, a central vacuum source, a number of end effectors located a number of work stations, and one or more connectors adjacent to the workstations for removably receiving or coupling to the end effectors. Such a system may further include a suitable network of pipes or conduits, and a flow or vacuum regulating feature associated with each connector to adjust the vacuum power or pressure at the working portion of the end effectors.

In one embodiment, the present invention comprises a system for managing fluid comprising: a vacuum source, an end effector spaced from the vacuum source, and a connector interposed between the vacuum source and end effector, the connector having at least one port for receiving both gaseous and liquid fluids. More than one end effector is coupled to the connector. The connector is adapted to separate liquid and gas. The connector is adapted to

regulate a vacuum applied by the end effector. The connector comprises a display, and may be provided with a display input.

In one embodiment, the present invention relates to a vacuum system for picking up fluids in an operating room, the system comprising: means for producing a vacuum and means for separating liquid and gas, both the means for producing a vacuum and means for separating liquid and gas remote from the operating room, means for applying the vacuum to a selected location in the operating room, means for defining a flow path operably coupling the means for producing a vacuum and the means for applying a vacuum, and means for operably coupling the means for applying a vacuum to the flow path. The means for operably coupling is adapted to separate liquid and gas. The means for operably coupling is adapted to regulate the vacuum applied by the end effector. The means for operably coupling comprises means for measuring a quantity of separated liquid, means for displaying the quantity, means for inputting liquid information, means for calculating a difference between the quantity of separated liquid and the liquid information, and means for displaying the quantity and the difference.

In one embodiment, the present invention comprises a vacuum system for picking up fluids and solids present in an operating room, the system comprising: a vacuum source comprising a vacuum producer and a centrifugal separator, at least one end effector, a flow path defined by conduit operably coupling the vacuum source and end effector, the flow path comprising a wall port, and a connector generally between the vacuum source and end effector and removably

coupled to the wall port, wherein the connector is adapted to separate liquid and gas. The connector further comprises a measuring device for measuring the amount of liquid picked up and a display device for displaying the amount of liquid picked up. The connector is adapted to separate liquids, gas and solids. The connector further comprises an input for inputting liquid information.

In one embodiment, the present invention relates to a central vacuum system for picking up fluids present at one or more locations at which surgical procedures are performed, the system comprising: a vacuum source comprising a vacuum producer and a centrifugal separator, the vacuum source remote from the one or more locations; a first end effector of one type and a second end effector of another type; a flow path defined by conduit operably coupling the vacuum source and end effectors, the flow path comprising at least one wall port at each of the one or more locations; and a connector generally between the vacuum source and end effector and removably coupled to the wall port, the connector adapted to removably receive the first and second end effectors and to separate liquid and gas and comprising a measuring device for measuring the amount of liquid picked up and a display device for displaying the amount of liquid picked up. The invention may further comprise an adaptor for adapting the connector to separate liquids, gas and solids. The connector further comprises an input for inputting liquid information.

In one embodiment, the present invention central vacuum system for picking up material present at one or more locations at which surgical procedures are performed, the system comprising: a vacuum source comprising a vacuum

producer and a centrifugal separator, the vacuum source remote from the one or more locations; a first end effector of one type and a second end effector of another type; a flow path defined by conduit operably coupling the vacuum source and end effectors, the flow path comprising at least one wall port at each of the one or more locations; and a connector generally between the vacuum source and end effectors and removably coupled to the wall port, the connector adapted to removably receive the first and second end effectors, to regulate the vacuum at the first and second end effectors, and to separate liquid and gas, and further comprising a measuring device for measuring the amount of liquid picked up, an input for inputting liquid information, a calculator for calculating a difference between the amount of liquid picked up and the input liquid information, and a display for displaying the amount of liquid picked up and the difference. The connector may be adapted to separate liquids, gas and solids.

The present invention may be embodied in other specific forms without departing from the essential spirit or attributes thereof. It is desired that described embodiments be considered in all respects as illustrative, not restrictive.

CLAIMS

What is claimed is:

1. A vacuum connector comprising:

an inlet;

an outlet;

a separation chamber in communication with the inlet;

an air pathway in communication with the separation chamber and the outlet; and

a fluid pathway separate from the air pathway, and in communication with the separation chamber and the outlet.

2. The connector of claim 1, and further comprising a flow indicator coupled to the fluid pathway.

3. The connector of claim 1, and further comprising a bioaerosol inlet separate from the inlet, and in communication with the outlet.

4. The connector of claim 1, and further comprising a volumetric indicator coupled to the fluid pathway.

5. The connector of claim 1, and further comprising a decontamination unit in cooperation with the outlet.

6. The connector of claim 1, and further comprising a collection chamber in communication with the separation chamber.

7. The connector of claim 1, and further comprising a vacuum regulator in cooperation with the inlet.

8. The connector of claim 1, and further comprising a flowmeter coupled to the fluid pathway, and a microprocessor in communication with the flowmeter and capable of calculating flow rates and total volume

9. The connector of claim 1, and further comprising an end effector in communication with the inlet.

10. The connector of claim 1, and further comprising a vacuum source in communication with the outlet.

11. The connector of claim 1, wherein the separation chamber includes a baffle in cooperation with the inlet for optimizing the separation of liquid and gaseous material.

12. The connector of claim 1, wherein the separation chamber includes a filter in cooperation with the inlet for optimizing the separation of solid materials.

13. A vacuum system comprising:

a vacuum source;

a connector in communication with the vacuum source and comprising of an inlet, an outlet, a separation chamber in communication with the inlet, an air pathway in communication with the separation chamber and the outlet, and a fluid pathway separate from the air pathway and in communication with the separation chamber and the outlet; and

an end effector in communication with the inlet.

14. The system of claim 13, and further comprising a flowmeter coupled to the fluid pathway, and a microprocessor in communication with the flowmeter and capable of calculating flow rates and total volume.

15. The system of claim 14, and further comprising an input device in communication with the microprocessor.

16. The system of claim 15, wherein the input device includes a key pad.

17. The system of claim 13, and further comprising a decontamination unit in cooperation with the outlet, the contamination unit including a collapsible container containing a pre-measured amount of decontaminant.

18. The system of claim of claim 13, wherein the vacuum source includes a centrifugal separator.

19. A method of calculating liquid information evacuated from a source containing liquid, solids, or gas, the method comprising:

providing a connector comprising of an inlet, an outlet, a separation chamber in communication with the inlet, an air pathway in communication with the separation chamber and the outlet, and a fluid pathway separate from the air pathway and in communication with the separation chamber and the outlet;

coupling an end effector in communication with the source to the inlet;

coupling a flow meter to the fluid pathway;

applying a vacuum pressure to the outlet; and

calculating liquid information from an output provided by the flow meter.

20. The method of claim 19, wherein two types of liquid information calculated is a flow rate and a total liquid volume.

ABSTRACT

The present invention comprises a central vacuum producing system suitable for collecting both liquid and gaseous material, one or more end effectors for use at a site at which liquid and gaseous material are produced, and a coupling device or connector for operably coupling one or more end effectors to the central vacuum. In this embodiment, the connector may be made of various materials, and may include a suitable liquid monitor or counter such as a flow meter.

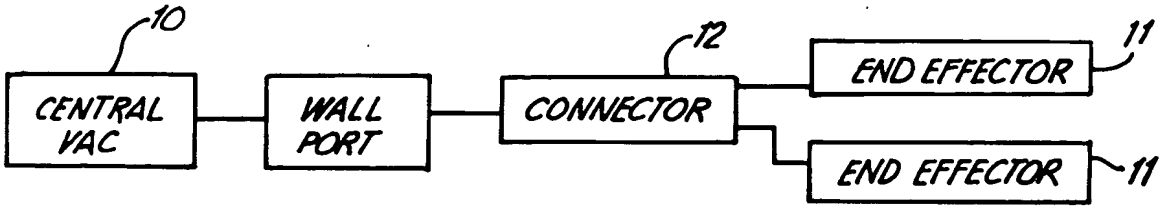

Fig. 1

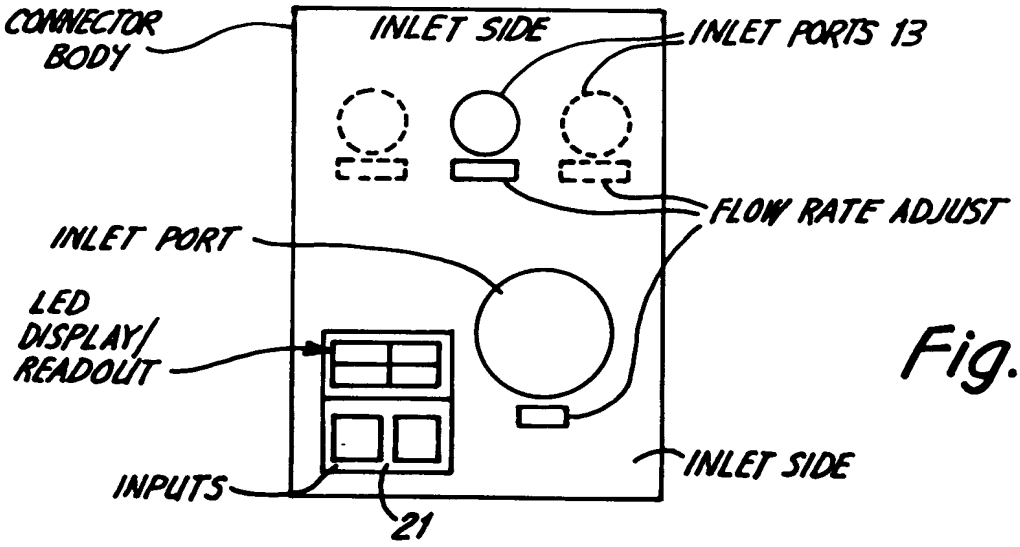

Fig. 3

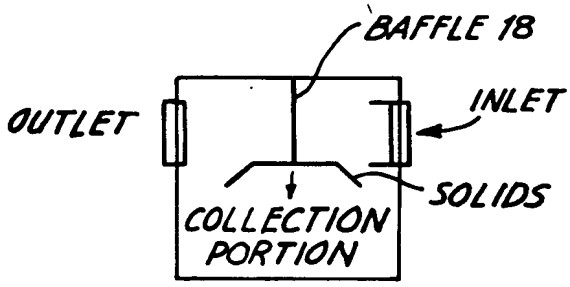

Fig. 5

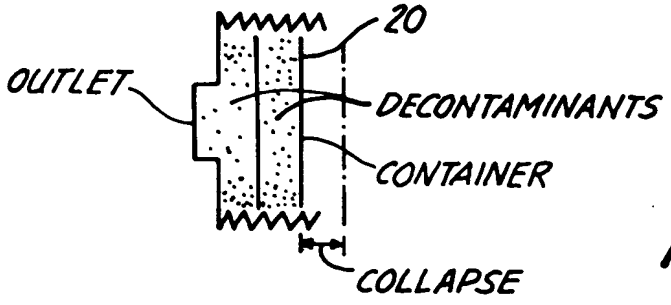

Fig. 6

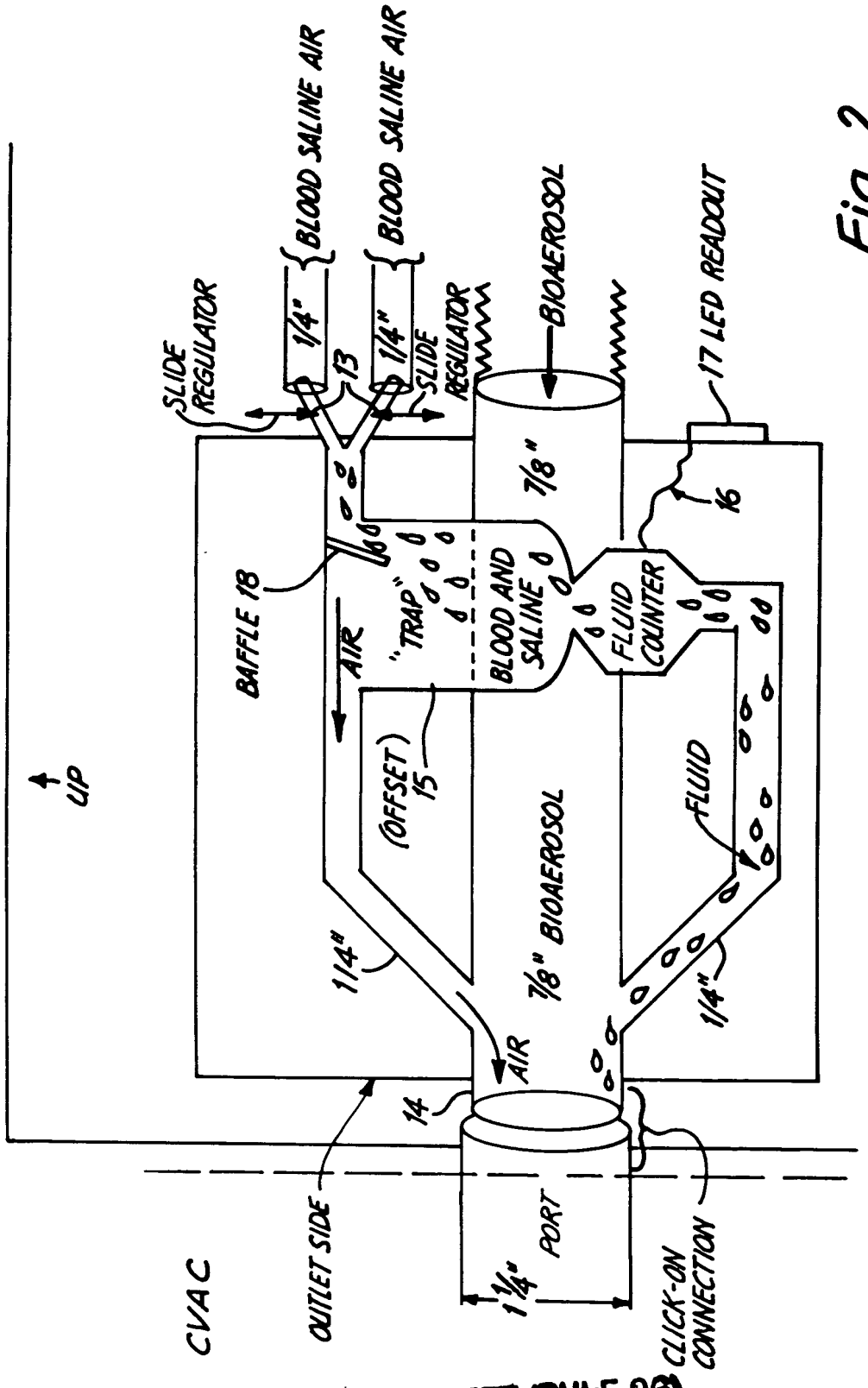
12
UP
SLIDE REGULATOR
1/4"
BLOOD SALINE AIR
13
1/4"
BLOOD SALINE AIR
SLIDE REGULATOR
BIOAEROSOL
17 LED READOUT
7/8"
16
BAFFLE 18
AIR
"TRAP"
BLOOD AND SALINE
FLUID COUNTER
(OFFSET) 15
FLUID
1/4"
7/8" BIOAEROSOL
1/4"
AIR
14
CVAC
OUTLET SIDE
1/4"
PORT
CLICK-ON CONNECTION

Fig. 2

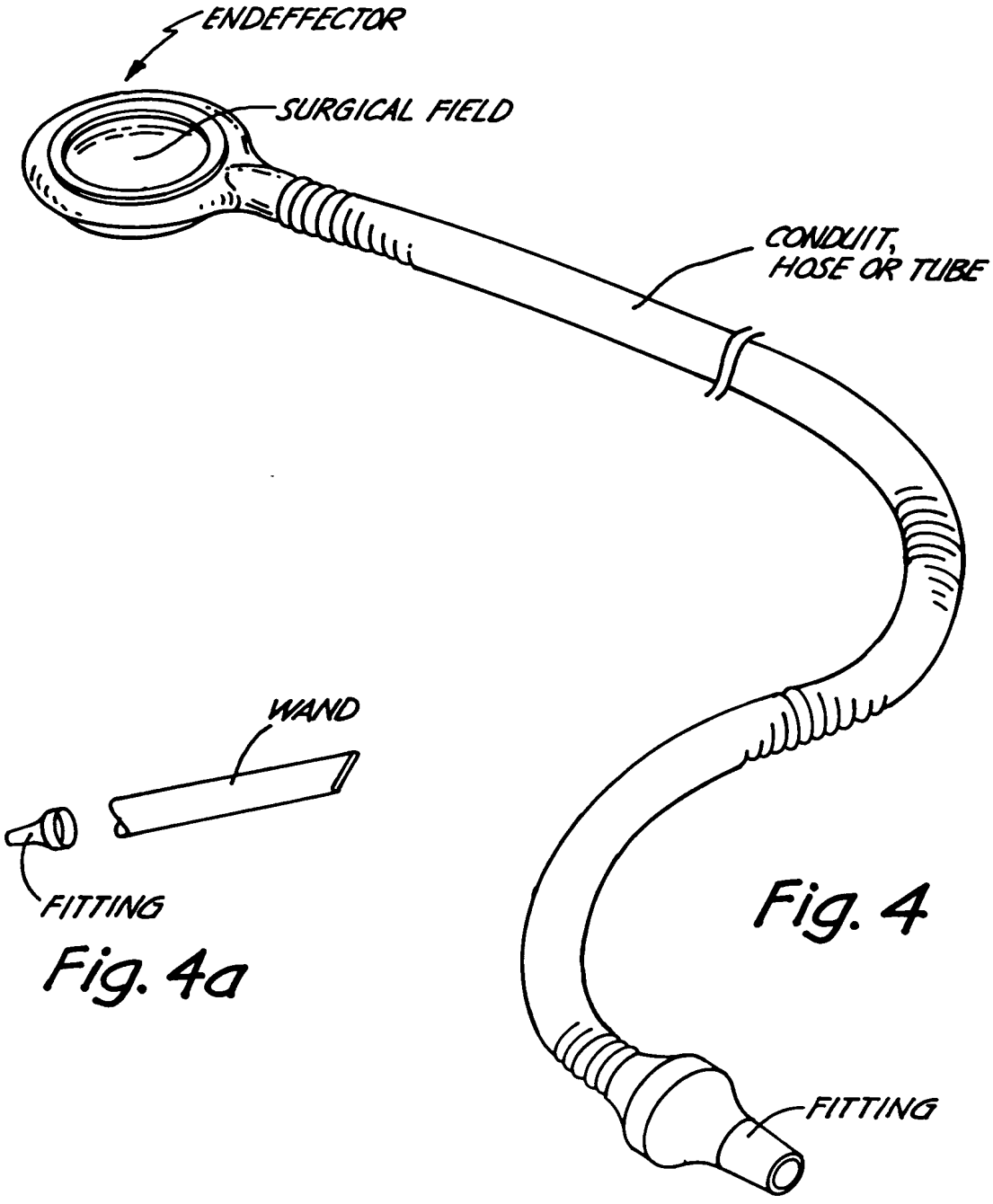

Fig. 4

Fig. 4a

344214InventoryList

"InventoryList"

"PCT/US02/02493"

"17 Sep 2002"

"1. RO111 Notification Relating to Priority Claim"
"2. RO123 Notification Concerning Representation"